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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,644	01/22/2004	Noa Zerangue	019282-001511US	8428

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EXAMINER

CHANDRA, GYAN

ART UNIT PAPER NUMBER

1646

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,644	ZERANGUE ET AL.	
	Examiner	Art Unit	
	Gyan Chandra	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1-8, in part, 9-10, 22, in part, drawn to an isolated polypeptide having at least 80% sequence identity to the SEQ ID NO: 2, an isolated nucleic acid encoding the polypeptide having at least 80% sequence identity to the SEQ ID NO: 2, an isolated nucleic acid encoding the polypeptide having at least 80% sequence identity to the SEQ ID NO: 2 operably linked to a heterologous promoter (vector), a host cell comprising the vector and a method of screening an agent, conjugate or conjugate moiety which is a substrate for the polypeptide .

Groups 2-4, claim(s) 1-3, in part, drawn to an isolated polypeptide having an amino acid sequence at least 80% identical to the amino acid sequence of SEQ ID NO: 4, 6 and 8, respectively.

Groups 5-8, claim(s) claims 4-7, in part, 25-27, drawn to an isolated nucleic acid sequence encoding the polypeptide having at least 80% identity to the polypeptide of SEQ ID NO: 4, 6, and 8, and the nucleic acid sequence of SEQ ID NO: 19, respectively.

Groups 9-12, claim(s) 11-12, drawn to a method of screening an agent, conjugate or conjugate moiety that binds to a transporter having at least 80% sequence identity to an amino acid sequence set forth in the SEQ ID NO: 2, 4, 6 and 8, respectively.

Groups 13-16, claim(s) 13, drawn to a conjugate comprising an agent linked to a conjugate moiety for a transporter having an amino acid sequence having at least 80% sequence identity to an amino acid sequence set forth in the SEQ ID NO: 2, 4, 6 and 8 wherein the agent has a pharmaceutical activity without the conjugate moiety, respectively.

Groups 17-20, claim(s) 14, drawn to a method of making a pharmaceutical composition comprising linking an agent to a conjugate moiety for a transporter having an amino

Art Unit: 1646

acid sequence with at least 80% sequence identity to an amino acid sequence set forth in the SEQ ID NO: 2, 4, 6 and 8 and formulating the conjugate with a carrier, respectively.

Groups 21-24, claim(s) 15-17, drawn to a method of treating a patient comprising administering a conjugate comprising an agent linked to a conjugate moiety for a transporter having an amino acid sequence having at least 80% sequence identity to an amino acid sequence set forth in the SEQ ID NO: 2, 4, 6 and 8, respectively.

Groups 25-28, claim(s) 19-21, drawn to an antibody and a method of producing the antibody that specifically binds to a protein selected from the group comprising an amino acid set forth in the SEQ ID NO: 2, 4, 6 and 8, respectively.

Groups 29-31, claim(s) 22, in part, drawn to a method of screening an agent, conjugate or conjugate moiety which is a substrate for a polypeptide selected from the group of the polypeptide of SEQ ID NO: 4, 6 and 8, respectively.

Groups 32-35, claim(s) 23-24, in part, drawn to a method of screening agents, conjugates or conjugate moieties for capacity to agonize a transporter comprising contacting a cell expressing a transporter comprising an amino acid selected from the group consisting of SEQ ID NO: 2, 4, 6 and 8, respectively.

Groups 36-39, claim(s) 23-24, in part, drawn to a method of screening agents, conjugates or conjugate moieties for capacity to antagonize a transporter comprising contacting a cell expressing a transporter comprising an amino acid selected from the group consisting of SEQ ID NO: 2, 4, 6 and 8, respectively.

The inventions listed as Groups 1-39 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

- I. Group 1, recites the special technical feature of an isolated polypeptide having at least 80% sequence identity to the SEQ ID NO: 2, an isolated nucleic acid encoding the polypeptide having at least 80% sequence identity to the SEQ ID NO: 2, an isolated nucleic acid encoding the polypeptide having at least 80% sequence identity to the SEQ ID NO: 2 operably linked to a heterologous promoter (vector), a host cell comprising the vector and a method of screening an agent, conjugate or conjugate moiety which is a substrate for the polypeptide, which is not required by other products of Groups 2-8, 13-16 and 25-28.

Art Unit: 1646

- II. Groups 2-4, recite the special technical feature of an isolated polypeptide having an amino acid sequence at least 80% identical to the amino acid sequence of SEQ ID NO: 4, 6 and 8, which is not required by other products of Groups 1, 5-8, 13-16 and 25-28.
- III. Groups 5-8, recite the special technical feature of an isolated nucleic acid sequence encoding the polypeptide having at least 80% identity to the polypeptide of SEQ ID NO: 4, 6, and 8, and the nucleic acid sequence of SEQ ID NO: 19, which is not required by other products of Groups 1-4, 13-16 and 25-28.
- IV. Groups 9-12, recite the special technical feature of screening an agent, conjugate or conjugate moiety that binds to a transporter having at least 80% sequence identity to an amino acid sequence set forth in the SEQ ID NO: 2, 4, 6 and 8, which is not required by other methods of Groups 17-20, 21-24, and 29-39.
- V. Group 13-16, recite the special technical feature of a conjugate comprising an agent linked to a conjugate moiety for a transporter having an amino acid sequence having at least 80% sequence identity to an amino acid sequence set forth in the SEQ ID NO: 2, 4, 6 and 8 wherein the agent has a pharmaceutical activity without the conjugate moiety, which is not required by other products of Groups 1-8, and 25-28.
- VI. Groups 17-20, recite the special technical feature of making a pharmaceutical composition comprising linking an agent to a conjugate moiety for a transporter having an amino acid sequence with at least 80% sequence identity to an amino acid sequence set forth in the SEQ ID NO: 2, 4, 6 and 8 and formulating the conjugate with a carrier, which is not required by other methods of Groups 9-12, 21-24, and 29-39.

Art Unit: 1646

- VII. Groups 21-24, recite the special technical feature of treating a patient comprising administering a conjugate comprising an agent linked to a conjugate moiety for a transporter having an amino acid sequence having at least 80% sequence identity to an amino acid sequence set forth in the SEQ ID NO: 2, 4, 6 and 8, which is not required by other methods of Groups 9-12, 17-20, and 29-39.
- VIII. Groups 25-28, recite the special technical feature of an antibody and a method of producing the antibody that specifically binds to a protein selected from the group comprising an amino acid set forth in the SEQ ID NO: 2, 4, 6 and 8, which is not required by other products of Groups 1-8, and 13-16.
- IX. Groups 29-31, recite the special technical feature of screening an agent, conjugate or conjugate moiety which is a substrate for a polypeptide selected from the group of the polypeptide of SEQ ID NO: 4, 6 and 8, which is not required by other methods of Groups 9-12, 17-24, and 32-39.
- X. Groups 32-35, recite the special technical feature of screening agents, conjugates or conjugate moieties for capacity to agonize a transporter comprising contacting a cell expressing a transporter comprising an amino acid selected from the group consisting of SEQ ID NO: 2, 4, 6 and 8, which is not required by other methods of Groups 9-12, 17-24, 29-31, and 36-39.
- XI. Groups 36-39, recite the special technical feature of screening agents, conjugates or conjugate moieties for capacity to antagonize a transporter comprising contacting a cell expressing a transporter comprising an amino acid selected from the group consisting of SEQ ID NO: 2, 4, 6 and 8, which is not required by other methods of Groups 9-12, 17-24, 29-31, and 32-35.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently

Art Unit: 1646

found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Art Unit: 1646

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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29 August 2006
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PRIMARY EXAMINER